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6713-Dr. Wi-ar
100718-67
Beiersdorf 514.1-KGB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	SCHÖNROCK et al.
SERIAL NO.	:	**09/132,799**
FILED	:	13 August 1998
FOR	:	COSMETIC OR DERMATOLOGICAL PREPARATIONS COMPRISING OLIGOPEPTIDES FOR LIGHTENING THE SKIN OF AGE MARKS AND/OR PREVENTING TANNING OF THE SKIN, IN PARTICULAR TANNING OF THE SKIN BY UV RADIATION
ART UNIT	:	1654
EXAMINER	:	Michael Borin

19 August 2004

Mail Stop: Petitions
Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO WITHDRAW HOLDING OF ABANDONMENT UNDER 37 CFR 1.181(a)

SIR:

According to the Notice of Abandonment dated 11 August 2004, this application abandoned for failure to respond to an Office Action mailed on 8 October 2002. However, the applicants filed a Notice of Appeal on 6 March 2003 and filed an Appeal Brief on 6 May 2003.

No fee is believed to be due in connection with the consideration of this petition. However, should the Commissioner determine that any fee is, in fact, due, he is hereby authorized to charge such fee to Deposit Account No. 14-1263.

In accordance with the procedure outlined in MPEP § 711.03(c) (I)(B), the undersigned hereby attests that the following statements are true:

(1) A Notice of Appeal was faxed by the undersigned's secretary to the PTO on 6 March 2003 using the fax number (703) 305-3014 cited by the Examiner on page 13 his Office Action mailed on 8 October 2003 and that the fax transmission sheet indicated that the fax was sent successfully to the PTO (see Exhibit A). The petition for Extension of Time erroneously asked for a one month

extension, however, the Notice of Appeal authorized the PTO to charge for any additional fees or extension of time as required.

(2) The applicants sent via Express Mail filed an Appeal Brief on 6 May 2003. Receipt of which by the United States Postal Service is verified by the stamped Express Mail label and was attested as being sent by Ms. Vilma Fernandez on the last page of the Appeal Brief (see Exhibit B - the postcard was sent to the PTO but was sent back to the applicants' representative on 12 May 2003 without a stamp.)

The applicants also note for the record that:

(a) a Status Letter (see Exhibit C) was sent to the PTO on 22 June 2004; and

(b) MPEP 711.04(a) states in part: "...applications should be carefully scrutinized by the appropriate examiner to verify that they are actually abandoned." In the spirit of good customer service and compact prosecution, it had been the applicants understanding that general PTO policy was to telephone the applicants representative (although there is no formal requirement to do so). However, the applicants have no record of a telephone conversation between the Examiner and the applicants' representative to verify that the application had been abandoned.

Three copies of the Appeal Brief of 6 May 2003 are submitted herewith so that prosecution can continue should the petition to withdraw holding of abandonment be granted.

Note: A CPA for this application was filed on 21 November 2000 and as such this application qualifies for patent term adjustment time which was believed to be +235 days as of the mailing of the Notice of Abandonment.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS MCLAUGHLIN & MARCUS, P.A.

By Howard C. Lee
Howard C. Lee
Reg. No. 48,104

220 East 42nd Street, 30th Floor
New York, New York 10017
(212) 808-0700

6713-Dr. Wi-ar
100718-67
Beiersdorf 514.1-KGB

Attachments:

Exhibit A:	Copy of fax cover sheet indicating successful transmission; copy of fax cover sheet; copy of Notice of Appeal; copy of Petition for Extension of Time
Exhibit B:	Copy of postcard dated May 6, 2003; copy of stamped Express Mail label; copy of Fee transmittal
Exhibit C:	Copy of status request

Three (3) copies of Appeal Brief sent on 6 May 2003

CERTIFICATE OF MAILING

I hereby certify that the foregoing Petition to Withdraw Holding of Abandonment is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below:

Date: **19 August 2004**

By Agata Glinska

Agata Glinska

Confirmation Report – Memory Send

Page : 001
Date & Time: Mar-06-03 04:41pm
Line 1 : +212 808 0844
Machine ID : Norris McLaughlin & Marcus

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Date	:	Mar-06 04:38pm
To	:	☎917033053014
Number of pages	:	005
Start time	:	Mar-06 04:38pm
End time	:	Mar-06 04:41pm
Pages sent	:	005
Status	:	OK

Job number : 608 *** SEND SUCCESSFUL ***

FACSIMILE COVER SHEET

NORRIS MCLAUGHLIN & MARCUS, P.A.
220 East 42nd Street
30th Floor
New York, New York 10017
Tel.: (212) 808-0700
Fax.: (212) 808-0844

Date: 6 March 2003

To: Examiner Michael Borin
US Patent and Trademark Office
Tel. 703-305-4506
Fax: 703-305-3014

Subject: USSN 09/132,799
Our Ref.: Beiersdorf 514.1

From: Howard C. Lee

Comments: Filing of Notice of Appeal (2 pgs.), and Petition for Extension of Time (2 pgs.).

If you have any questions or need further information, please contact us.

You should receive 5 pages including this cover sheet.

FACSIMILE COVER SHEET

NORRIS MCLAUGHLIN & MARCUS, P.A.
220 East 42nd Street
30th Floor
New York, New York 10017
Tel.: (212) 808-0700
Fax.: (212) 808-0844

Date: **6 March 2003**

To: Examiner Michael Borin
US Patent and Trademark Office
Tel. 703-305-4506
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Subject: USSN 09/132,799
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From: Howard C. Lee

Comments: Filing of Notice of Appeal (2 pgs.), and Petition for Extension of Time (2 pgs.).

If you have any questions or need further information, please contact us.

You should receive 5 pages including this cover sheet.

Attorney Docket No. Beiersdorf 514.1-HCL
6713-Dr. Wi-ar

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	SCHÖNROCK et al.
SERIAL NO.	:	09/132,799
FILED	:	13 August 1998
FOR	:	COSMETIC OR DERMATOLGICAL PREPARATIONS COMPRISING OLIGOPEPTIDES FOR LIGHTENING THE SKIN OF AGE MARKS AND/OR PREVENTING TANNING OF THE SKIN, IN PARTICULAR TANNING OF THE SKIN BY UV RADIATION
ART UNIT	:	1631
EXAMINER	:	Michael L. Borin

---

6 March 2003

Box AF
Hon. Commissioner of Patents
Washington, D.C. 20231

NOTICE OF APPEAL

Applicants hereby appeal to the Board of Appeals from the Final Office Action dated 8 October 2002, of the primary Examiner finally rejecting Claims 6, 11, 12, 14-20, and 22.

The period for response to the final rejection was set to expire on 8 January 2003. Such period was extended one (1) month by a Petition for Extension of Time, filed herewith.

Charge the appeal fee of:

[X] $320.00
[ ] $160.00 - Small Entity

to Deposit Account No. 14-1263.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, applicants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,

NORRIS, McLAUGHLIN & MARCUS, P.A.

By Howard C. Lee
Howard C. Lee
Reg. No. 48,104

HCL/vif

220 East 42nd Street, 30th Floor
New York, New York 10017

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted via facsimile addressed to: Box AF, Hon. Assistant Commissioner for Patents, Washington, D.C. 20231 on the date indicated below.

NORRIS, MCLAUGHLIN & MARCUS, P.A.

Date: 6 March 2003

By: _____
Vilma I. Fernandez

Attorney Docket No. Beiersdorf 514.1-HCL
6713-Dr. Wi-ar

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	SCHÖNROCK et al.
SERIAL NO.	:	09/132,799
FILED	:	21 December 2000
FOR	:	COSMETIC OR DERMATOLGICAL PREPARATIONS COMPRISING OLIGOPEPTIDES FOR LIGHTENING THE SKIN OF AGE MARKS AND/OR PREVENTING TANNING OF THE SKIN, IN PARTICULAR TANNING OF THE SKIN BY UV RADIATION
ART UNIT	:	1631
EXAMINER	:	Michael L. Borin

6 March 2003

Box AF
Hon. Commissioner of Patents
Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME (37 CFR1.136(a))

Sir:

1. This is a petition to extend the period of time one (1) month for filing a response to the Office Action dated 8 October 2002.

2. Applicant is:

[ ] a small entity
[X] other than small entity

3.

Extension (months)	Fee for other than small entity	Fee for small entity
[x] one month	$ 110.00	$ 55.00
[ ] two months	$ 410.00	$205.00
[ ] three months	$ 930.00	$465.00
[ ] four months	$1,450.00	$725.00
[ ] five months	$1,970.00	$985.00

Attorney Docket No. Beiersdorf 514.1-HCL
6713-Dr. Wi-ar

Fee $ 110.00

4. A Notice of Appeal is filed herewith.

5. Charge the petition fee to Deposit Account No. 14-1263 and for any additional fee required or credit for any excess fee paid.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By: Howard C. Lee
Howard C. Lee
Reg. No. 48,104

220 East 42nd Street
30th Floor
New York, New York 10017
(212) 808-0700

HCL:vif

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Petition for Extension of Time (2 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 6 March 2003

By: _____
Vilma I. Fernandez

EV 208798564 US

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FROM: (PLEASE PRINT) PHONE (212) 808-0700

NORRIS MCLAUGHLIN &
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NEW YORK NY 10017-5806

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USPS MAY 2003

Barnes. 5/14.1-KGB

TO: (PLEASE PRINT) PHONE ( )

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EMS

CASE # Beiersdorf 514.1-KGB **Serial No.** 09/132,799

DATE MAILED: 6 May 2003 **,DATE DUE:**

The stamp of the Patent Office hereon may be taken as acknowledgement of receipt, on the date stamped, of the following:

1. Fee Transmittal (in duplicate)
2. Appellants' Brief on Appeal (in triplicate)

EV 208798564 US

RECEIVED

MAY 12 2003

NORRIS, MCLAUGHLIN & MARCUS, PA

NORRIS, McLAUGHLIN & MARCUS
220 EAST 42ND ST.
30TH FLOOR
NEW YORK, NEW YORK 10017

PTO/SB/17 (1-03)
Approved for use through 04/30/2003. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) $320.00

Complete if Known	
Application Number	09/132,799
Filing Date	13 August 1998
First Named Inventor	SCHONROCK et al.
Examiner Name	Michael Borin
Group Art Unit	1654
Attorney Docket No.	Beiersdorf 514.1-KGB

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 14-1263

Deposit Account Name:

The Commissioner is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☐ Charge any additonal fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** = 0	X	= 0.00
Independent Claims		- 3** = 0	X	= 0.00
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) $0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non - English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	320.00
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Statement	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) $320.00

SUBMITTED BY

Complete *(if applicable)*

Name (Print/Type)	Howard C. Lee	Registration No. (Attorney/Agent)	48,104	Telephone	(212) 808-0700
Signature	Howard C. Lee			Date	6 May 2003

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Attorney's Docket No: 100718-67/Beiersdorf 514.1-KGB/HCL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:UWE SCHONROCK etal
SERIAL NO.	:09/132,799
FILED	:AUGUST 13, 1998
FOR	:COSMETIC OR DERMATOLOGICAL PREPARATIONS COMPRISING OLIGOPEPTIDES FOR LIGHTENING THE SKIN OF AGE MARKS AND/OR PREVENTING TANNING OF THE SKIN, IN PARTICULAR TANNING OF THE SKIN BY UV RADIATION
GROUP ART UNIT	:1654
EXAMINER	:MICHAEL BORIN

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22323-1450

STATUS LETTER

Sir:

The records of the undersigned indicate that the above identified application should have been taken up for action by the Patent Office. No action, however, has as yet been received, so that the Patent Office's advice as to the status of the application is respectfully solicited

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS PA

By Howard C. Lee
Howard C. Lee
Reg. No. 48,104

220 East 42nd Street 30Fl
New York, NY 10017
(212) 808-0700

MAILING CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22323-1450 on:

Agata Gliszka June 22, 2004

6713-Dr. Wi-ar
Beiersdorf 514.1-KGB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANTS	:	SCHÖNROCK et al.
SERIAL NO.	:	**09/132,799**
FILED	:	13 August 1998
FOR	:	COSMETIC OR DERMATOLOGICAL PREPARATIONS COMPRISING OLIGOPEPTIDES FOR LIGHTENING THE SKIN OF AGE MARKS AND/OR PREVENTING TANNING OF THE SKIN, IN PARTICULAR TANNING OF THE SKIN BY UV RADIATION
ART UNIT	:	**1654**
EXAMINER	:	**Michael Borin**

6 May 2003

Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF ON APPEAL PURSUANT TO 37 CFR § 1.192

SIR:

This is an appeal from the final rejection dated 8 October 2002.

(1) REAL PARTY IN INTEREST

The real party in interest is **Beiersdorf AG** by virtue of an assignment recorded on at Reel 9552, Frame 0283 (Recorded on 19 October 1998).

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

(3) STATUS OF CLAIMS

Claims 6 and 11-26 are pending in the application. Claims 13, 21 and 23-26 have been withdrawn from consideration. Claims 6, 11, 12, 14-20 and 22 are subject to final rejection.

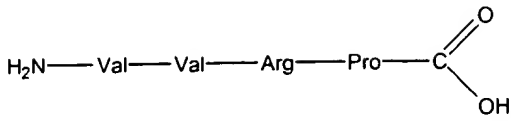
(4) STATUS OF AMENDMENTS

It is believed that all amendments have been entered (no amendment was submitted after the final rejection of 8 October 2002).

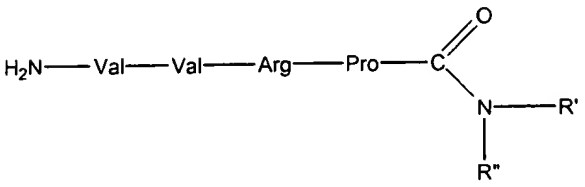
NOTE: A petition against the finality of the restriction/election of species requirement was filed on 13 January 2003 which was denied in the petition decision of 19 March 2003. A petition for reconsideration of the petition decision was filed on 6 May 2003. Should the restriction/election of species be rescinded, claim 21 would also be considered to be pending in the application.

(5) SUMMARY OF INVENTION

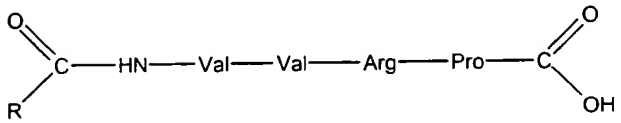
The present invention relates to a cosmetic or dermatological topical water-in-oil preparation for cosmetic and topical dermatological lightening of the skin or preventing tanning of the skin caused by UV radiation which comprises of one or more monomeric oligopeptides selected from the group consisting of:

(a) 

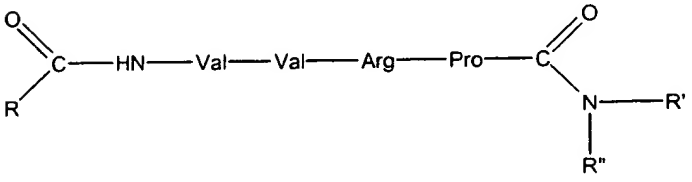
;

(b) 

;

(c) 

; and

(d) 

,

wherein:

R represents a branched or unbranched, saturated or unsaturated alkyl radical having C_1-C_{30} carbon atoms,

R' and R" independently of one another may be selected from the group consisting of hydrogen and branched or unbranched, saturated of unsaturated alkyl radical having C_1-C_{30} carbon atoms,

one or more cosmetically or dermatologically acceptable active ingredients, auxiliaries and/or additives; and

a cosmetically or dermatologically acceptable carrier.

This invention is supported, for example, by original claim 2 and pages 6-9 of the specification. Claims 6, 11, 12, 15-20 and 22 represent further limitations of this invention.

(6) ISSUES

The issues to be decided are whether:

1. Claims 14 and 15 are obvious or unobvious over Kohmura et al. (*Agric. Biol. Chem.*, 54: 835-836, (1990)) and Stein (U.S. Patent 5,346,887) in view of Goodman & Gilman's "The Pharmacological Basis of Therapeutics (Ninth Edition, page 745) and further in view of Greene et al. (U.S. Patent 5,753,226);

2. Claims 14 and 15 are obvious or unobvious over Kohmura et al. (*Agric. Biol. Chem.*, 54: 835-836, (1990)) and Stein (U.S. Patent 5,346,887) in view of Goodman & Gilman's "The Pharmacological Basis of Therapeutics (Ninth Edition, page 745) and further in view of Cho et al. (U.S. Patent 5,665,700);

3. Claims 14-20 and 22 are obvious or unobvious over Kohmura et al. (*Agric. Biol. Chem.*, 54: 835-836, (1990)) in view of Bundgaard (*Design of Prodrugs*, Chapter 1, 1985) and Sumner-Smith (U.S. Patent 5,646,120); and

4. Claims 14, 6, 11 and 12 are obvious or unobvious over Kohmura et al. (*Agric. Biol. Chem.*, 54: 835-836, (1990)) in view of Stein (U.S. Patent 5,346,887), Goodman & Gilman's "The Pharmacological Basis of Therapeutics (Ninth Edition, page 745), Bundgaard (*Design of Prodrugs*, Chapter 1, 1985) and Sumner-Smith (U.S. Patent 5,646,120).

(All references hereafter cited by single name)

(7) GROUPING OF CLAIMS

It is believed that should any of the rejections of claim 14 be reversed, the rejection of all of claims 6, 11, 12, 14-20 and 22 would be reversed. Based on the references cited, claims 14 and 15 could be considered to stand or fall together. However, claims 6, 11, 12 (specific dosage amounts) and claims 16-20 and 22 (specific tetrapeptides) should also be considered on their

separate merits.

(8) ARGUMENT

Summary of Arguments

The appellants composition claims are unobvious over any permutation of the secondary references when combined with Kohmura.

Secondarily, the primary reference (Kohmura) only describes the tetrapeptide VVRP like that of (a) in claim 14. There is no teaching or suggestion of the modified tetrapeptide VVRP like that of (b)-(d) in claim 14 which serves as the basis for dependent claims 16-20 and 22.

Underlying Issues to Be Decided

Before addressing the individually rejections in greater detail, it is believed that it would be helpful to frame the issues which form the basis for the positions held by the appellants and are believed to form the positions of the examiner.

The issues to be decided when determining whether the claims are obvious or unobvious over the prior art are:

(1) If a compound is known, can a composition based on that compound be held to be allowable?

(2) What weight, if any, should be accorded to the preamble of a claim?

The appellants believe an adequate representation of the examiner's position on these issues can be found, e.g., on page 7, lines 3-15 of the examiner's final rejection:

> "It would be *prima facie* obvious to one skilled in the art to be motivated to prepare pharmaceutical compositions from peptides of Komura (sic) because they have a desirable pharmaceutical properties of ACE inhibitors. Selection of a particular physical form of delivery would be within the perview (sic) of a person skilled in [the] art. For example, an artisan would be motivated to use water-in-oil formulation which has proven to be effective for oral administration of various

types of polypeptides, as illustrated in U.S. 5,665,700.

In regard to intended use recited in the preamble of claim 1 [now 14], arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. A mere statement of purpose or intended use in the preamble of a claim need not be considered in finding anticipation[1] Diversitech Corp. V. Century Steps, Inc. 7USPQ2d 1315 (Fed. Cir. 1988); In re Stencel, 4 USPQ2d 1071 (Fed. Cir. 1987)."

The appellants believe that since the ultimate determination whether an invention would have been obvious under 35 U.S.C. § 103 is a legal conclusion based on underlying findings of fact (see *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000), one of ordinary skill in the art cannot presume that a compound renders a composition containing that compound to be obvious or that the preamble does not breathe life and meaning into a composition claim until the facts of the case have been considered.

Compositions Containing Known Compounds

Some case law which provides guidance in this area include:

(a) *In re Rosicky*, 276 F.2d 656, 125 USPQ 341 (CCPA 1970) and *In re Lerner*, F.2d 1008, 169 USPQ 51 (CCPA 1971) - Claiming an otherwise patentably compound in combination with a carrier does not render the combination patentable ***if the prior art suggested utilizing the carrier with the compound***.

(b) *In re Wiggins*, 397 F.2d 356, 158 USPQ 199 (CCPA 1968) - A pharmaceutical compound for analgesic use containing an old compound, a pharmaceutical diluent, and a prescribed dosage form and amount was found to be unobvious over prior art describing the identical compound for use in protecting mice against the effects of x-ray radiation.

Weight Accorded the Preamble

MPEP 2111.02 (Weight of Preamble) recites that (bold and italics added by writer):

[1] It is reminded that all of the rejections under Appeal are based on obviousness not anticipation. Moreover, *Diversitech* also teaches that "Where preamble is essential to point out the claimed invention and give meaning and vitality to the claim, it is given the effect of a limitiaton."

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "***If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim.***" *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).....

PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "***can be resolved only on review of the entirety of the [record]*** to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works,* 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997)."

In addition, quoting from Chemical Patent Practice (1994) by John L. White:

"There is no general rule as to the weight given preambles as positive limitations affecting the patentability of the claimed subject matter. *In re Neugebauer et al.*, 330 F.2d 353, 141 USPQ 205 (CCPA 1964). ***Its significance is determined on the basis of the facts in each case.*** *In re Duva*, 387 F.2d 402, 156 USPQ 90 (CCPA 1967)...Where the language of a composition claim is otherwise so broad as to read on inoperable formulations, a preamble which recites the desired property (abrasive article) can have the effect of limiting the scope of the claim to the operative formulations. *Kropa v. Robie et al.*, 187 F.2d 150, 88 USPQ 478 (CCPA 1951)."

Statement of the Facts (Kohmura reference)

The Kohmura reference serves as the primary reference for each of the four rejections made under 103(a). The appellants concede that the Kohmura teaches the tetrapeptide VVRP which is identical to structure (a) of claim 14 - see Table 1, No. 6 of the Kohmura reference. (However, the modified VVRP like that of (b)-(d) in claim 14 are not disclosed by Kohmura.)

Kohmura also disclose other peptide sequences which differ from the tetrapeptide VVRP by chain

length or by type of amino acids used. Each of the VRP-containing peptides, including VVRP, were assayed for angiotensin-converting enzyme (ACE) activity (ACE inhibitors compounds are commonly used in anti-hypertension and blood pressure control compositions - some brand name examples include Vasotec and Prinivil).

Even within the context of ACE activity, VVRP is not a favored compound as indicated in col. 5, last 5 lines through page 836, col. 1, line 1 - "Elongation of the peptide chain of Val-Arg-Pro [VRP] one by one towards its N-terminus gave compounds **6-11**; ***as the size of the peptide increased, the potency decreased***, but further elongation of the peptide chain restored the potency and finally resulted in the comparatively potent compound **11** (57-65)." Of the compounds tested in this sequence, i.e. compounds 5-11 from Table 1 of Kohmura, VVRP represented the compound with the least amount of potency as an ACE-inhibitor.

It is also instructive to note that the final sentence of the Kohmura reference reads - "Further work, however, will be needed to conclude whether these active peptides have a physiological meaning in blood pressure regulation."

1. Kohmura and Stein in view of Goodman & Gilman's and Greene (claims 14 and 15)

Kohmura

Kohmura is relied upon for their teaching of the VVRP tetrapeptide and their use as a potential pharmaceutical agent, i.e. as an ACE-inhibitor. The only difference ascribed between the Kohmura reference and the appellants' invention is that Kohmura "does not teach administration of the referenced peptide in a form of pharmaceutical composition."

The appellants' respectfully disagree with this characterization of differences between the teachings of Kohmura and the appellants' claimed invention.

The appellants' claimed composition differ from the teachings of Kohmura in additional ways:

(a) They are directed toward cosmetic and dermatological compositions not pharmaceutical compositions;

(b) Not only do the appellants' claim a composition, but also a specific type of composition, i.e. a "topical water-in-oil-preparation";

(c) The cosmetic or dermatological composition also contains cosmetically or dermatologically acceptable active ingredients, auxiliaries and/or additives and a cosmetic or dermatologically acceptable carrier; and

(d) The specific preparation is also to said to have a specific property associated with it. i.e. "dermatological lightening of the skin or preventing tanning of the skin caused by UV radiation.

As recited in *Kropa v. Robie et al.*, supra, failure to include the intended use of the composition could've rendered the appellants' claim so broad as to read upon inoperable elements. As such, this preamble limitation alone would breath life and meaning into the claim. However, when considering the entirety of the preamble, it is evident that the serves not only to distinguish between compound and composition but among different types of compositions.

Stein and Goodman & Gilman

While it is certainly permissible to use secondary references and possibly combine or substitute their teachings with that of the primary reference, use of a secondary reference does not absolve the examiner from adhering to the "as a whole"-standard for considering the reference, especially with regard to disclosures which teach away from the appellants' invention.

Stein is referred to by the examiners as teaching "...topical compositions comprising ACE inhibitors. Said compositions are used to treat glaucoma. It would have been obvious to one skilled in the art at the time the invention was made to be motivated to prepare a topical pharmaceutical composition comprising peptides of Kohmura as an active ingredient, because Kohmura teaches that these peptides inhibit ACE activity and

as such they can be used in topical pharmaceutical compositions of Stein." (see page 4, lines 4-10 of examiner's final rejection)

However, these descriptions represent a mischaracterization of the teachings of Stein.

First, it should be pointed out that Stein refers to topical ***ocular*** compositions (see e.g. claim 6) which is not surprising for a composition directed toward treatment of glaucoma.

Second, the ACE-inhibitors of disclosed in Stein (e.g. captopril and enalapril) are not tetrapeptide sequences as in the appellants' claimed invention. It is noted that prosecution of this application also included a restriction and election of species requirement whereby the examiner established the patentable distinction between mono-, di-, tri- and tetra-peptides (homo- or hetero-peptides). The examiner cannot now argue that these same sequences are obvious over one another (captopril and enalapril are based on tripeptide sequences)

Third, the examiner's description of Stein would lead the reader to believe that the ACE-inhibitors were the primary ingredient of their topical ocular composition just as the VVRP tetrapeptides are the primary compounds of the appellants' composition. Rather, Stein teaches compositions and method of treating glaucoma which comprise of a therapeutically effective amount of a renin-inhibiting compound in combination with a therapeutically effective amount of a steroidal anti-inflammatory agent. It is only within the context that other ingredients could be added that ACE-inhibitors are part of the topical ocular composition.

Fourth, related to the third point above, one cannot separate the use of ACE-inhibitors in composition form from the renin-inhibiting compound in combination with a steroid anti-inflammatory agent. It has previously been held that *"[i]t is impermissible* within the framework of section 103 *to pick and choose* from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (see *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965)) and that "...*'Determination of obviousness cannot be based on the hindsight combination of*

components selectively culled from the prior art to fit the parameters of the patented invention.' see *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). Stein acknowledges that ACE-inhibitors have some undesirable side effects and suggests combination with a renin inhibitor to address this problem which inextricably links these two elements of Stein's invention (see col. 22, lines 21-29).

Goodman & Gilmans' is relied upon for the quote from page 745 that "there is no compelling reason to favor one ACE-inhibitor over another, since all ACE-inhibitors have...similar therapeutic indications, adverse affect profiles and contraindications." However, this selective reading also does not comply with the "as a whole"-standard for consideration. This reference was first introduced as Exhibit 1 with the appellants' response of 26 August 2001 and was relied upon by the appellants' for the teaching that ACE-inhibitors occasionally cause a maculopapular rash that may or may not itch (see page 751, paragraph entitled "Skin Rash", i.e. this represents a teaching away from the use of an ACE-inhibitor in a ***dermatological*** composition.

Within the purview of one skilled in the art is not the proper standard to establish a prima facie case of obviousness

With regard to the physical form of the preparation (i.e. a topical water-in-oil preparation), the examiner states that "...selection of a particular physical form of preparation is within the perview (sic) of one skilled in the art. For example, Greene et al. (U.S. Patent 5,753,226) describes peptide formulations for topical treatment of ocular and skin sites." (see page 4, lines 16-18 of examiner's final rejection).

However, MPEP 2143.01 states that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993)."

No motivation to combine the references as asserted by the examiner

In addition to the lack of motivation for obtaining a particular physical form as described above, the motivation for combining the teachings of Stein and Goodman & Gliman's appear to come from hindsight reconstruction by the examiner and not from any explicit or implicit suggestion from the prior art.

The Kohmura reference is not suggestive of a composition much less a cosmetic or dermatological topical water-in-oil composition. As mentioned above in the Statement of Facts (Kohmura), if motivation is based on the teaching in Kohmura for ACE-inhibitor activity for the forming a composition with VVRP, it is again reminded that VVRP was the least attractive of the VRP-peptides which would teach against their further use and that Kohmura themselves acknowledged that further studies would have to be undertaken before their use as blood pressure regulators could be determined.

Both Stein and Goodman & Gilman lack any suggestion or direction that the selective teachings relied upon by the examiner could be substituted into the teachings of Kohmura and that one would be directed to make this substitution. MPEP 2143 states that "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)"

MPEP 2143.01 establishes that "The mere fact that references *can be combined* or modified *does not render the resultant combination obvious unless* the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)". Given the teachings of Stein and Goodman & Gilman, reasonable doubts exist as to whether the references could be combined with Kohmura.

For all of the above reasons, the appellants' claimed composition is not suggested by the compound of Kohmura when viewing Kohmura and the secondary references as a whole and as such an *In re Rosicky*, supra or *In re Lerner*, supra, type situation does not exist here.

Even if all of these references were combined as indicated by the examiner, this still would leave one of ordinary skill in the art with a pharmaceutical composition not a

cosmetic or dermatological topical water-in-oil composition for lightening of the skin or preventing tanning of the skin caused by UV radiation. This would be problematic for maintaining the rejection on a couple of levels.

First, it would be presumed through inherency that the pharmaceutical composition formed would also be a topical cosmetic or dermatological composition and that in the process of forming the pharmaceutical composition, the activity of lightening the skin or preventing tanning would be retained. However, no evidence has been presented in establishing inherency for this point.

MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof) states "*The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).....To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), see also *Mentor H/S, Inc. v. Medical Device Alliance, Inc. (Mentor II)*, 244 F.3d 1365, 58 USPQ2d 1321 (Fed. Cir. 2001) and *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Second, even if inherency was shown, there is still no teaching or direction which would lead one to pick a water-in-oil form for the composition.

2. **Kohmura and Stein in view of Goodman & Gilman's and Cho**

The reader is referred to the appellants' previous points and arguments made above with respect to the Kohmura, Stein and Goodman & Gliman references.

Within the purview of one skilled in the art is not the proper standard to establish a prima facie case of obviousness

This rejection is similar to 1. above with the only difference being the substitution of Greene with Cho.

With regard to the physical form of the preparation (i.e. a topical water-in-oil preparation), the examiner states that "Selection of a particular physical form of preparation is within the perview (sic) of one skilled in the art. For example, an artisan would be motivated to use water-in-oil formulation which has been proven to be effective for oral administration of various types of polypeptides, as illustrated in US 5,665,700." (see page 7, lines 5-9 of examiner's final rejection).

However, MPEP 2143.01 states that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993)."

Moreover, the peptides referred to in Cho are not directed to tetrapeptide sequences as in the appellants' claimed invention (see e.g. claim 4 - insulin, erythropoietin, porcine somatotropin, human growth hormone or calcitonin). It is noted that prosecution of this application also included a restriction and election of species requirement whereby the examiner established the patentable distinction between mono-, di-, tri- and tetra-peptides (homo- or hetero-peptides). The examiner cannot now argue that these same sequences are obvious over one another.

3. **Kohmura in view of Bundgaard and Sumner-Smith (Claims 14-20 and 22)**

The reader is referred to the appellants' previous points and arguments made above with respect to the Kohmura reference.

Can be modified is not the proper standard for combining references

Bundgaard and Sumner-Smith establish that terminal amino groups and carboxyl groups of tetrapeptides could be modified. However, what is lacking is a motivation which

arises from the references themselves which suggesting making such a modification to the VVRP tetrapeptide of Kohmura.

MPEP 2143.01 establishes that "The mere fact that references *can be combined* or modified *does not render the resultant combination obvious unless* the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)".

Moreover, even the examiner's hindsight logic for making the modification to the VVRP tetrapeptide of Kohmura is open to question. The examiner stated that "...a prodrug analog having protected N- and/or C-termini with a reasonable expectation that such prodrugs will have at least similar effectiveness in inhibition of angiotension-converting enzyme and regulation of related physiological processes." (see page 9, lines 3-7 of examiner's final rejection)

First, as recited in the Statement of Facts (Kohmura), supra, Kohmura themselves acknowledge the need for further testing to establish a link between their disclosed ACE-inhibition activity and a physiological process such as blood pressure regulation.

Second, the state of the art with regard to the VRP-class of peptides has a certain degree of unpredictability assigned to it. Tri-peptides had the best ACE-inhibition activity of the VRP-class while tetra-peptide and penta-peptide showed the worst ACE-inhibition activity. VRP-class peptides of 6-9 amino acids showed worse activity than tri-peptides but still at least three orders of magnitude better than tetrapeptides (see Table 1 of Kohmura). Therefore, there is no reasonable expectation of success for a holding of maintaining "similar effectiveness".

All claim limitations not taught

MPEP 2143.03 states that "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." (see also *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

Even if it were to be upheld that the combination of references teaches the appellants' invention as it relates to claim 14, structures (a) and (b) (and also claims 15, 16 and 19) claims 17, 18, 20 and 22 are directed toward separate subject matter not taught by Kohmura in combination with Bundgaard and Sumner-Smith (structures (c) and (d) lack an amino terminus). There is no reason beyond an "obvious-to-try" rationale which would support the modifications to the VVRP tetrapeptide sequence to arrive at the tetrapeptides of claims 17, 18, 20 and 22.

4. **Kohmura in view of Stein, Goodman & Gilman, Bundgaard and Sumner-Smith (Claims 14, 6, 11 and 12)**

The reader is referred to the appellants' previous points and arguments made above with respect to the Kohmura, Stein, Goodman & Gilman, Bundgaard and Sumner-Smith references.

It is believed that the appellants previous responses have established that one of ordinary skill in the art would not even arrive at the point where the cosmetic or dermatological topical water-in-oil preparation could be obtained and that all which remained was to arrive at the appellants' specifically claimed dosage ranges. It would also appear that the precedent of *In re Wiggins*, supra, would also apply here.

However, *in arguendo*, even if a composition were somehow established, the examiner is relying upon the premise that the ranges taught by Kohmura fall within the ranges taught by the appellants and that any differences would fall under the purview of optimization the ranges of an art recognized variable.

This should not be persuasive on at least two counts.

First, the examiner's assumptions are based on an *in vitro* formulation for ACE-inhibition with no teaching or suggestion that this is intended for a topical water-in-oil preparation.

Second, while the motivation for any modification of the Kohmura reference, does not have to match that of the appellants' invention, the final composition form must meet

the limitations set forth in the appellants' claims. There is no indication that within the process of modifying the teachings of Kohmura to match the dosage limitations of claims 6, 11 and 12, that one of ordinary skill in the art would simultaneously be able to maintain the limitations set forth in independent claim 14, i.e. cosmetic or dermatological topical water-in-oil preparation for cosmetic and topical dermatological lightening of the skin or preventing tanning of the skin caused by UV radiation.

Both of these propositions appear to have basis in inherency, but no evidentiary support has been provided to establish these claims. MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof) states "*The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).....To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), see also *Mentor H/S, Inc. v. Medical Device Alliance, Inc. (Mentor II)*, 244 F.3d 1365, 58 USPQ2d 1321 (Fed. Cir. 2001) and *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

(9) CONCLUSION

For the foregoing reasons, Appellants respectfully request that the Honorable Board reverse the obviousness rejections against claims 6, 11, 12, 14-20 and 22.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Appellants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess to our Deposit Account No. 14-1263.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Label EV 208798564 US, in an envelope addressed to: Hon. Commissioner of Patents, P.O. Box 1450 Alexandria, VA 22313-1450

Date: **6 May 2003**

By: Vilma I. Fernandez

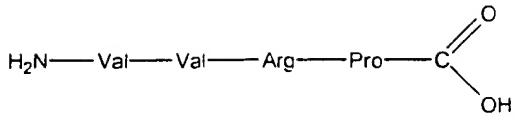
(10) **APPENDIX** - CLAIMS ON APPEAL

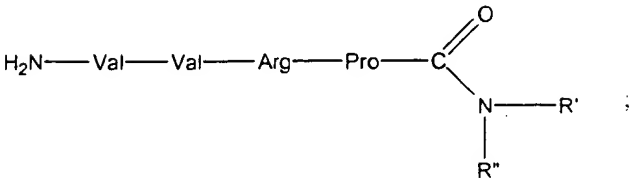
6. The topical water-in-oil preparation of claim 14, wherein the oligopeptides(s) is/are present in cosmetic or dermatological topical preparations in concentration of 0.000001 -10% by weight, based on the total weight of the preparations.

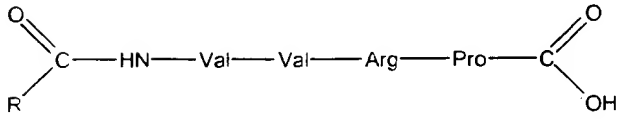
11. The topical water-in-oil preparation of claim 6, wherein the oligopeptides(s) is/are present in the cosmetic or dermatological topical preparations in concentrations of 0.0001 – 1% by weight based on the total weight of the preparations.

12. The topical water-in-oil preparation of claim 11, wherein the oligopeptides(s) is/are present in the cosmetic or dermatological topical preparations in concentrations of 0.0001 – 0.1% by weight based on the total weight of the preparations.

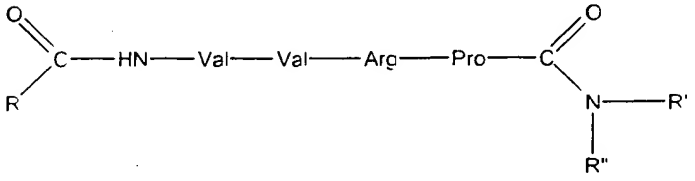
14. A cosmetic or dermatological topical water-in-oil preparation for cosmetic and topical dermatological lightening of the skin or preventing tanning of the skin caused by UV radiation which comprises of one or more monomeric oligopeptides selected from the group consisting of:

(a) 

(b) 

(c) 

; and

(d) 

,

wherein:

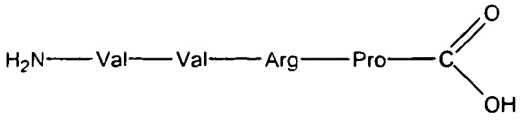
R represents a branched or unbranched, saturated or unsaturated alkyl radical having C_1-C_{30} carbon atoms,

R' and R" independently of one another may be selected from the group consisting of hydrogen and branched or unbranched, saturated of unsaturated alkyl radical having C_1-C_{30} carbon atoms,

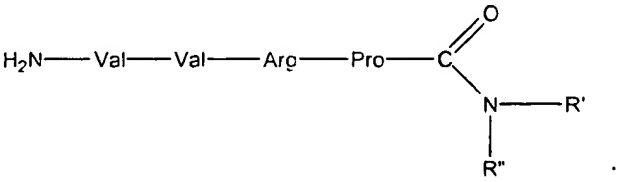
one or more cosmetically or dermatologically acceptable active ingredients, auxiliaries and/or additives; and

a cosmetically or dermatologically acceptable carrier.

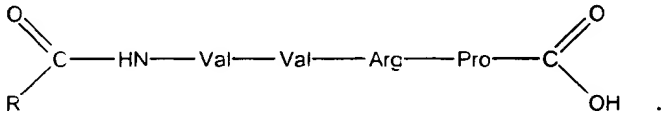
15. The cosmetic or dermatological topical water-in-oil preparation of claim 14 wherein the oligopeptide is

(a) 

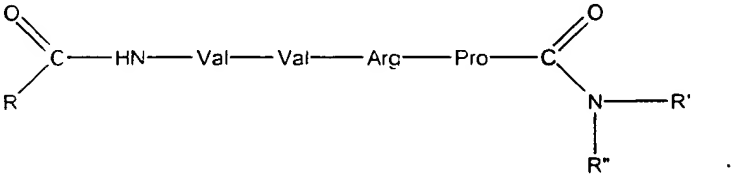
16. The cosmetic or dermatological topical water-in-oil preparation of claim 14 wherein the oligopeptide is

(b) 

17. The cosmetic or dermatological topical water-in-oil preparation of claim 14 wherein the oligopeptide is

(c) 

18. The cosmetic or dermatological topical water-in-oil preparation of claim 14 wherein the oligopeptide is

(d) 

19. The cosmetic or dermatological topical water-in-oil preparation of claim 16 wherein R' and R" is hydrogen.

20. The cosmetic or dermatological topical water-in-oil preparation of claim 17 wherein R is methyl.

21. The cosmetic or dermatological topical water-in-oil preparation of claim 17 wherein R is an n-C_{15} or n-C_{17} alkyl radical.

22. The cosmetic of dermatological topical water-in-oil preparation of claim 18 wherein R is methyl, R' is hydrogen and R" is hydrogen.